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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,880	07/27/2001	Hugh Semple Munro	27020/37611	8935

7590

06/04/2003

Carl E. Moore, Jr.
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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT

PAPER NUMBER

1615

10

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/916,880

Applicant(s)

MUNRO ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-47,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-47,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 2.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Interview Summary	Application N .	Applicant(s)	
	09/916,880	MUNRO ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) Liliana Di Nola-Baron. (3)_____.

(2) Gerald Shekleton. (4)_____.

Date of Interview: 22 April 2003.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The examiner has asked the attorney to kindly provide a copy of the allowed claims of the U.S. application 09/771004, which has been recently allowed and is in the process of being published, since the case is currently unavailable. The examiner has additionally asked the attorney to possibly provide a terminal disclaimer, if the claims in the allowed application require so.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DETAILED ACTION

Receipt of Applicant's amendment, filed on March 3 and April 25, 2003, and terminal disclaimer, filed on April 25, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19-47, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz et al. (WO 95/20634 or WO 97/05171).

Dietz et al. provides a bicontinuous pressure sensitive adhesive polymerization product, wherein both the oil and water phase coexist in interconnected continuous domains (See p. 1), and teaches that the hydrophobic and hydrophilic phases are formed as hydrophobic and hydrophilic monomers polymerize (See p. 5). Dietz et al. teaches that the pressure sensitive polymerization product of the invention comprises 2-60% of water, 2-90% of hydrophilic monomer, 5-85% of hydrophobic monomer, 2-70% of a surfactant selected from the groups of nonionic, cationic and anionic surfactants, and optionally plasticizers and tackifiers (See pp. 7-8), thus the prior art discloses the ingredients claimed in claims 19-22, 28, 30, 34-37, 43 and 46 of the instant application in the ranges claimed by Applicant.

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Dietz et al. provides a method comprising mixing together the hydrophilic, amphiphilic and hydrophobic monomers and the surfactants and adding water to the mixture, and teaches that there is no dispersed phase, isolated from continuity in the composition (See pp. 9-11). Thus, even though Dietz et al. does not define the mixture as homogeneous, as claimed by Applicant in claims 19-47, 52 and 53, the prior art discloses a reaction mixture comprising both the hydrophilic and the hydrophobic components, and teaches that the hydrophobic and hydrophilic phases are formed as hydrophobic and hydrophilic monomers polymerize, thus contemplating the definition of “homogeneous” given by Applicant in the specification. Furthermore, as claimed in claims 25-27 and 31-33 of the instant application, Dietz et al. includes 2-acrylamido-2-methylpropane sulfonic acid and N,N-dimethylacrylamide (NNDMA) among the polar monomers known in the art to exhibit some solubility in both water and oil (See p. 15 or p. 16), and said compounds, according to Applicant’s specification (See p. 26) provide for a homogeneous reaction mixture, wherein seemingly incompatible components are intimately mixed.

Regarding claims 23 and 24, Dietz et al. provides a skin adhesion test (See p. 47 or p. 49) and reports adhesion values of 460g/2.54 cm (See Examples 21 and 22). Said values are not expressed in the same units claimed by Applicant. The burden is shifted to Applicant, to show that the amount of adhesion provided by the prior art is different from the amount claimed by Applicant.

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With respect to claims 29, 39-42, 44, 45 and 47, Dietz et al. provides glycerin and polyalkylene glycols among the water-soluble additives used as plasticizers, n-butyl acrylate as preferred hydrophobic monomer, and styrene and vinyl esters, such as vinyl acetate, among the comonomers in the organic phase (See pp.15-19).

Regarding claim 38, Dietz et al. teaches that the oil phase may comprise oil-soluble additives and includes Pluronic, which includes ethylene oxide-propylene oxide block copolymers, among the surfactants used in the invention (See pp. 22-24).

With respect to claims 52 and 53, the references teach that the polymerized products may be used as biomedical electrodes and medical skin coverings (See pp. 34 and 41 in WO 95/20634 and pp. 36 and 43 in WO 97/05171).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Dietz et al. to provide bioadhesive compositions suitable for medical applications. The expected result would have been a successful bioadhesive composition for use in a biomedical skin electrode or in a wound dressing. Because of the teachings of Dietz et al., that polymerized biphasic emulsion can be used to produce medical bioadhesive compositions, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

3. Applicant's arguments filed on March 3, 2003 have been fully considered but they are not persuasive.

4. Applicant argues that the invention is directed to a bioadhesive composition, which is the product of polymerizing a homogeneous aqueous reaction, and the references teach products of polymerizing microemulsions, which are phase-segregated at all stages before polymerization. In response to said argument, it is noted that Dietz et al. provides a bicontinuous pressure sensitive adhesive polymerization product, wherein both the oil and water phase coexist in interconnected continuous domains (See p. 1), and teaches that the hydrophobic and hydrophilic phases are formed as hydrophobic and hydrophilic monomers polymerize (See p. 5). Dietz et al. provides a method comprising mixing together the hydrophilic, amphiphilic and hydrophobic monomers and the surfactants and adding water to the mixture, and teaches that there is no dispersed phase, isolated from continuity in the composition (See pp. 9-11). Thus, even though Dietz et al. does not define the mixture as homogeneous, as claimed by Applicant in claims 19-47, 52 and 53, the prior art discloses a reaction mixture comprising both the hydrophilic and the hydrophobic components, and teaches that the hydrophobic and hydrophilic phases are formed as hydrophobic and hydrophilic monomers polymerize, thus contemplating the definition of "homogeneous" given by Applicant in the specification. Furthermore, as claimed in claims 25-27 and 31-33 of the instant application, Dietz et al. includes 2-acrylamido-2-methylpropane sulfonic acid and N,N-dimethylacrylamide (NNDMA) among the polar monomers known in the art to exhibit some solubility in both water and oil (See p. 15 or p. 16), and said compounds, according to Applicant's specification (See p. 26) provide for a homogeneous reaction mixture, wherein

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seemingly incompatible components are intimately mixed. Thus, the prior art contemplates homogeneous reaction mixtures.

5. In response to Applicant's argument, that the examples provided by the prior art do not include a plasticizer, it is noted that the disclosure of the prior art clearly states that the compositions of the invention comprise a plasticizer and provides glycerin and polyalkylene glycols among the water-soluble additives used as plasticizers (See p. 17 or 18). The examples in the prior art are the inventor's best mode, and it is not necessary for the prior art's best mode to contemplate the specific combinations claimed by Applicant.

6. In reply to Applicant's argument, that the prior art does not teach or suggest homogeneous pre-polymerization mixture with added plasticizer, it is noted, as replied above, that the prior art discloses a reaction mixture comprising both the hydrophilic and the hydrophobic components, and teaches that the hydrophobic and hydrophilic phases are formed as hydrophobic and hydrophilic monomers polymerize, thus contemplating the definition of "homogeneous" given by Applicant in the specification. Furthermore, as claimed in claims 25-27 and 31-33 of the instant application, Dietz et al. includes 2-acrylamido-2-methylpropane sulfonic acid and N,N-dimethylacrylamide (NNDMA) among the polar monomers known in the art to exhibit some solubility in both water and oil (See p. 15 or p. 16), and said compounds, according to Applicant's specification (See p. 26) provide for a homogeneous reaction mixture, wherein seemingly incompatible components are intimately mixed. Additionally, the disclosure of the prior art clearly states that the compositions of the invention comprise a plasticizer and provides glycerin and polyalkylene glycols among the water-soluble additives used as plasticizers (See p. 17 or 18).

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7. In response to Applicant's argument, that the claimed invention has defined hydrophobic regions embebbbed in a hydrophilic matrix, it is noted that said feature is not recited in the rejected claims.

Conclusion

8. Claims 19-47, 52 and 53 stand rejected.

9. Applicant's amendment has overcome the 35 U.S.C. 112, second paragraph rejections of claims 19, 21-47 and 51 of the previous Office action. Accordingly, said rejections are withdrawn.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Long

May 23, 2003

Thurman K. Page
THURMAN K. PAGE
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TECHNOLOGY CENTER 1600